

C3
activating means [inserted] insertable in said downstream coupling means through said outlet opening for moving said plug means towards an upstream open position where said needle means does pass through said plug means.

Claim 23, line 2, delete "resilient means is a";
line 2, following "spring", insert --is a
helical spring--.

REMARKS

This Amendment is being submitted in response to the Official Action dated December 8, 1993 and following a telephone interview with Examiner Alexander on January 31, 1994. The undersigned attorney of record appreciates the time that the Examiner took in discussing the Official Action of December 8, 1993, the references cited therein and the rejected claims. It is believed that the telephone interview was beneficial in at least two respects: (1) it provided the Examiner with information as to Applicant believes that there are important differences between the features of the check valve disclosed in Kilmarx United States Patent No. 3,352,531, one of the cited references, and the features of the connector disclosed and claimed in the above-identified application and (2) it provided the undersigned

Serial No. 07/980,547

and the Examiner an opportunity to discuss how the rejected claims were being interpreted by the Examiner. As a result of that telephone interview and further consideration of the cited references and the claims presently under consideration in the above-identified application, claims 1 and 22-23 have been amended. Additionally, other dependent claims have been amended so that those claims conform to the amended independent claims. As is discussed in more detail below, it is respectfully submitted that with the entry of this Amendment, the connector as specified in the claims still pending in the above-identified application is patentable over the cited references, whether those references are considered individually or together. Accordingly, the allowance of the above-identified application is solicited.

In connection with discussing the rejected claims based upon what is disclosed in the cited references, i.e., the Kilmarx patent and/or Bonaldo United States Patent No. 5,154,703, it is believed appropriate to set forth what was discussed in the telephone interview with Examiner Alexander on January 31, 1994. In this regard, the Examiner has issued an Examiner Interview Summary Record dated February 2, 1994. As indicated above, the operation and structure of both the check valve disclosed in the Kilmarx patent and the connector disclosed and claimed in the

above-identified application were discussed during that telephone interview.

The Kilmarx patent discloses a check valve 10 that includes a pin 13 extending through an O-ring 12. In FIG. 1 of the Kilmarx patent, the check valve 10 is illustrated in its closed condition. In such a closed condition, the pin 13 is extending through the O-ring 12 into bore portions 11a and 11b. The check valve 10 is closed due to the fact that the O-ring 12 is seated against a valve seat 11f. In order to open the check valve 10, a hollow needle 17 is inserted into the bore portions 11a and 11b as illustrated in FIG. 3 in the Kilmarx patent. The insertion of the needle 17 in this manner results in the O-ring 12 being pushed away from the valve seat 11f so that fluid can flow through the check valve 10 as indicated by the arrows in FIG. 3 of the Kilmarx patent. As is particularly apparent from FIG. 1, the bore portions 11a and 11b in the check valve 10 of the Kilmarx patent are completely open to the surrounding environment when the check valve 10 is in its closed condition. As a result, contaminants from the surrounding environment can readily enter those bore portions 11a and 11b before the valve is used (as, for example, when it is in its closed condition illustrated in FIG. 1). Once the check valve 10 is placed in its open condition illustrated in FIG. 3, any such contaminants including bacteria will be introduced into the slot 13g of the pin 13.

While the Kilmarx patent indicates that the check valve 10 can be used with "a catheter" (Kilmarx patent, column 1, lines 9-11), the check valve 10 cannot be used in connection with medical applications where there is a substantial risk of contaminants entering such a device. This is because the bore portions 11a and 11b remain open to the surrounding area so that bacteria could enter those bore portions whenever the check valve 10 is its open condition illustrated in FIG. 1 of the Kilmarx patent.

Another aspect of the check valve 10 that was discussed during the telephone interview involved the pin 13 and how it is situated within the O-ring 12 in both the open and closed conditions of the check valve 10. In this regard, the pin 13 is shown as extending through the O-ring 12 in both FIGS. 1 and 3 of the Kilmarx patent. Consequently, the O-ring 12 does not have a property of recapturing its closure condition if a needle was withdrawn from it. To the contrary, an O-ring typically has a fixed central opening.

One of the important features of the connector disclosed and claimed in the above-identified application that also was discussed in the telephone interview is the complete filling of the outlet opening 7a and 7b of the downstream coupling by material of the plug (including portions 4a, 4b and 4c) when the plug is in its closure position (see FIG. 2 of the above-identified application). It is this complete filling of the

Serial No. 07/980,547

outlet opening 7a and 7b by the material of the plug that prevents contamination of the downstream passage before the connector is used.

Another feature of the connector of the above-identified application that was discussed in the telephone interview was how the needle 3 was positioned vis-a-vis the plug. When the connector is in its closed condition (for example, as illustrated in FIG. 2 of the above-identified application), the needle 3 does not project through the plug. As a result, the plug closes off the downstream passage because of its property of recapturing its closure condition whenever the needle 3 is not extending through it. On the other hand, the needle 3 is extended through the plug when the plug is pushed away from the downstream outlet opening (for example, as illustrated in FIG. 3 of the above-identified application) in order to place the downstream passage in fluid communication with the upstream passage of the connector disclosed in the above-identified application.

It is the above discussed features of the connector disclosed in the above-identified application that makes it significantly different in operation and structure from devices disclosed in the cited references. These features are specifically set forth in claims 1 and 22 of the above-identified application and the fact that these features were set forth in those claims was discussed with the Examiner during the telephone

interview. While it was believed that claims 1 and 22 prior to the above amendments adequately recited these features, claims 1 and 22 have been further amended to more particularly set forth the important characteristics of the connector disclosed in the above-identified application and to overcome concerns voiced by the Examiner during the telephone interview as to the manner in which some of these characteristics were set forth in those claims.

Claims 1 and 22 now define the connector of the above-identified application as having a chamber extending between an upstream coupling means having an upstream passage that extends from the chamber toward an upstream end of the connector. The connector also includes a downstream coupling means having a downstream passage that extends from the chamber to a downstream outlet opening of the connector. A hollow needle is fixed in the upstream passage and is adapted to connect the upstream passage to the downstream passage. In a downstream stable closure condition of the connector, a plug is resiliently urged by a spring means into the downstream passage and the needle is not passed through the plug. The plug is made of material that recaptures its closure properties whenever the needle is not extending through the plug and consequently, the plug closes the downstream passage. Moreover, the plug completely fills the downstream outlet opening so as to prevent any dead volume to be

at the downstream outlet opening so that bacteria or other contaminants will not enter the downstream passage. The plug can be urged to an upstream open position when a member is inserted into the downstream passage. When so urged to such an upstream position, the needle will be forced through the plug resulting in the downstream passage being placed in fluid communication with the upstream passage.

As is discussed above, the Kilmarx patent does not have any type of needle that in a closed condition of the valve does not extend through a plug that recaptures its closure properties whenever the needle is not extending through the plug. To the contrary, the pin 13 disclosed in the Kilmarx patent extends through the O-ring 12 when the check valve 10 is closed (FIG. 1) or open (FIG. 3). Moreover, the O-ring 12 does not appear to have any type of recapture properties. In fact, most O-rings have a preformed central circular opening. In addition, the check valve 10 in the Kilmarx patent, unlike the connector disclosed and claimed in the above-identified application, does not have a plug that completely fills a downstream outlet opening. As is also discussed above, the bore portions 11a and 11b in the check valve 10 are completely open to the surrounding environment when the check valve 10 is closed (see FIG. 1 of the Kilmarx patent). As a result, bacteria and other contaminants can enter those bore portions 11a and 11b. In the connector recited in

claims 1 and 22, the plug is defined as completely filling the downstream outlet opening when the connector is in its closed condition. The complete filling of this downstream outlet opening insures that bacteria and other contaminants do not enter the connector before a member is inserted into the connector to place the downstream and upstream passages in fluid communication.

In the Official Action, the Examiner has rejected claims 1-5, 8, 9 12-14 and 22-23 under 35 U.S.C. §102(b) as being anticipated by the check valve disclosed in the Kilmarx patent. It is believed apparent from the above discussion that what is disclosed in the Kilmarx patent does not anticipate what is now set forth in the independent claims 1 and 22 because the connector defined in those claims contain significant features that are not disclosed in the Kilmarx patent. Nor does the Kilmarx patent in any way suggest these important features. To the contrary, the above discussion conclusively establishes that the check valve of the Kilmarx patent and connector defined in the rejected claims 1 and 22 operate in a significantly different manner and the results obtained by the connector of those claims is significantly different from the results obtained by the check valve disclosed in the Kilmarx patent. Consequently, the check valve disclosed in the Kilmarx patent does not render obvious the con-

Serial No. 07/980,547

necter defined in claims 1 and 22. Accordingly, the allowance of claims 1 and 22 is solicited.

The other claims rejected as being anticipated by the check valve disclosed in the Kilmarx patent, i.e., claims 2-5, 8-10, 12-13 (claim 14 has been deleted) and 23, are each dependent on claim 1 or 22 and further define the connector set forth in those claims. It is believed that the connector as defined in those dependent claims is patentable for at least the reasons discussed above with respect to claims 1 and 22. Accordingly, the allowance of claims 2-5, 8-10, 12-13 and 23 is solicited.

The Examiner has rejected the connector defined in claim 10 under 35 U.S.C. §103 as being rendered obvious by the bloodless catheter disclosed in the Bonaldo patent in view of the check valve disclosed in the Kilmarx patent. Claim 10 is dependent on claim 1 and is believed patentable over the cited references for at least the reasons set forth above with respect to claim 1. Accordingly, the allowance of claim 1 is solicited.

In response to the Official Action dated April 27, 1993, claims 1-5, 8-10, 12-14 and 22-23 were elected to be prosecuted in connection with the above-identified application. However, the Examiner did indicate in that Official Action that the remaining claims, i.e., claims 6, 11 and 15-21, would be considered if a generic claim was allowed. As set forth above, it respectfully submitted that claims 1 and 22 are in a condition

Serial No. 07/980,547

for allowance. In view of the fact that those claims are considered generic to the different species disclosed in the above-identified application, it is requested that those claims also be considered allowable for at least the reasons set forth above with respect to claim 1, the claim on which claims 6, 11 and 15-21 are dependent. These claims are believed patentable over the cited references for at least the reasons set forth above with respect to claim 1 and accordingly, the allowance of claims 6, 11 and 15-21 is solicited.

If the claims are allowed as being requested, the objection to the drawings that was made in connection with the Official Action dated June 30, 1993 can be overcome as discussed in the Amendment filed September 27, 1993 and at that time, this application will be in a condition for allowance and such action will be solicited.

Respectfully submitted,

MASON, KOLEHMAINEN, RATHBURN & WYSS

By



Joseph Krieger

Reg. No. 25,595

Telephone: 312/697-2400